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(54) **HIGH-PROTEIN HIGH-VISCOSITY ALIMENTARY FOOD COMPOSITION.**

(57) A high-protein high-viscosity alimentary food composition comprising, on a dry weight basis, 40 to 65 wt % of protein, 5 to 25 wt % of fat and 15 to 40 wt % of carbohydrate, and having a viscosity ranging from 500 ~ 3,000 cP as determined at 30 °C with a Brookfield viscometer and an amino acid score of 80 or above with a 2- to 5-year-old child as a reference standard.

## INDUSTRIAL FIELD OF UTILIZATION

The present invention relates to a nutritive food composition and more particularly to a high-protein, high-viscosity nutritive food composition which is rich in proteins of high quality.

## PRIOR ART AND ITS PROBLEMS

Recent years have witnessed an increased consciousness of health, shapeup and dieting and the consequent increase in the sporting population dedicated to jogging, cycling and mountaineering. Under the circumstances, the present invention has as an object to provide a food composition enabling an easy and expedient intake of high-quality protein necessary for energy supplementation in sport activities and an augmentation of body protein, such as the muscle, under the condition of increased protein assimilation of the body during physical exercises for body building, shapeup and other purposes. It is another object of the present invention to provide a food composition which can be utilized as a space food to be supplied in squeeze-tubes, for instance. A still another object of the invention is to provide a high-protein, high-viscosity nutritive food composition for hospitalized patients which is rich in high quality protein and lean in water and can be ingested easily and conveniently even by bed-ridden patients in postoperative convalescence or in the course of recovery from liver disease, or patients with renal failure.

The inventors of the present invention explored this field of formula feeding to satisfy the above requirements and found that a food composition having the formulation and rheological profile defined below is a very effective nutritive food meeting the above requirements and the use of this particular composition enables us to satisfy the need for intensive nutrition of patients with said diseases or for shapeup and body building of healthy persons. The present invention is predicated on the above finding.

## DISCLOSURE OF THE INVENTION

In accordance with the present invention there is provided a high-protein, high-viscosity nutritive food composition characterized in that it is composed, on a dry weight basis, 40 to 65% (% by weight; the same applies hereinafter) of protein, 5 to 25% of fat and 15 to 40% of carbohydrate and has a viscosity in the range of 500 to 3,000 cp (at 30°C, Type B viscosimeter) and an amino acid score (on a 2-5-year-old infant basis) of not less than 80.

As used in this specification, the term "amino acid score (on a 2-5-year-old infant basis)" means the score based on the following amino acid score pattern adopted by the Joint FAO/WHO/UNU Ad Hoc Expert Committee of 1985.

Abbreviation of amino acid	Essential amino acids per unit protein (mg/g protein*)
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His	19
Ile	28
Leu	66
Lys	58
Cys	25
Tyr	63
Thr	34
Trp	11
Val	35

Total	
(His included)	339
(His excluded)	320

The amount of protein\* is calculated by the formula "Nitrogen x 6.25".

By virtue of the above-defined formula, the food composition of the present invention can, on oral or enteral feeding, supply adequate calorie and nutrients according to an energy feeding, muscle building or shapeup protocol or expedite postoperative restoration of body protein.

The nutritive food composition of the present invention is now described in detail. The composition of the invention can be manufactured by the established production technology for nutritive food preparations of this kind except that it is so arranged that the final composition contains the above-specified amounts of protein, fat and carbohydrate and has a viscosity and an amino acid score in the respective ranges defined hereinbefore.

The protein mentioned above includes, among others, casein and its salts, gelatin and its salts, water-soluble gelatin (e.g. enzymatically degraded gelatin), whole milk, skim milk, soybean protein, corn gluten meal, wheat protein and so on. The fat includes, among others, soybean oil, olive oil, medium-chain triglycerides (MCT), cottonseed oil, sunflower oil, cacao butter, sesame oil, rice oil, safflower oil, peanut oil, rapeseed oil and so on. The carbohydrate includes, among others, dextrin, sucrose, monosaccharides such as fructose, glucose, etc., sugar alcohols such as erythritol, disaccharides such as malt sugar or maltose, and oligosaccharides such as fructo oligosaccharides, lactooligosaccharides, galactosylactose, lactosucrose and so on.

The proportions of the above ingredients in the food composition of the invention are chosen from within the following ranges.

Ingredient	Permissible range (wt.%)	Preferred range (wt.%)
Protein	40-65	40-53
Fat	5-25	10-18
Carbohydrate	15-40	20-35

It should be understood that the indicated amount of protein is the amount of pure protein as determined by measuring the nitrogen content of the respective proteinous materials by Kjeldahl's method.

In the high-protein, high-viscosity nutritive food composition of the invention, there may be incorporated various additives where necessary. The additives may be these commonly used in nutritive foods of this kind. Thus, among such additives are various vitamins, minerals, synthetic flavoring substances and natural flavor concentrates, natural sweeteners (sorbitin, stevia, etc.), synthetic sweeteners (saccharin, stevia extract, aspartame, etc.), colorants, flavors (cheese, chocolate, etc.), and dietary fibers such as polydextrose, pectic acid and its salts, alginic acid and its salts, etc. and these additives can be used singly or in combination. While the proportion of such additives is more or less optional, it is generally chosen from within the range of 0 to about 20 parts by weight based on 100 parts by weight of the total composition of the invention.

The composition of the present invention can be manufactured by mixing the above ingredients in any optional manner. For example, all the ingredients may be mixed together in one operation. An alternative procedure comprises adding as an auxiliary emulsifier, e.g. protein, carbohydrate, etc., and where necessary an emulsifying agent, e.g. lecithin, sugar esters, etc., to a mixture of fat-soluble materials (fats, oils and other fat-soluble components) and emulsifying the resulting mixture mechanically in the routine manner to provide a composition of the invention.

The resulting composition of the invention (the food of the invention in a liquid form) can be filled into an appropriate container and sterilized by retorting (120°C, 20 minutes) to provide a product having a sufficient shelf life. This product can be used directly or as appropriately diluted.

The food composition of the invention thus manufactured insures decomposition (digestion) and absorption at appropriate rates in the intestinal tract and is low in osmolality. Therefore, it can exhibit its nutritional condition-improving effect effectively and in a steady manner, substantially without the risk of causing diarrhea in the recipient. The amount of the food per intake is preferably chosen from within the range of about 10 to 30 g on a dry basis or, on a bulk volume basis, about 50 to 300 cc.

The food composition of the present invention can be advantageously utilized for supplying nutrients to patients who require oral, pernasal or enteral nutrition. It is also a nourishing food (or beverage) for healthy persons. The use of this food is conducive to effective energy supplementation, muscle building, protein augmentation, shapup, etc. and, moreover, offers the advantage that it can be simply and easily ingested.

The food according to the invention is also of use as a food for increasing body protein for purposes of muscle building, shapup, etc. as well as a space food to be ingested from squeeze-tubes. Moreover, unlike preparations administered intravenously, e.g. by intravenous drip, the composition is physiological and can be utilized universally for all patients needing improved nutritional homeostasis.

The benefits that can be realized from the use of the food of the present invention include improvements in various parameters or indicators of nutrition, such as total protein, albumin, nitrogen balance, cholesterol, triglyceride value, triceps muscle of arm, thickness of subcutaneous fat at brachial muscle, prealbumin, retinol, transferrin, body weight, total cholesterol, triglycerides, HDL-C, apoprotein, free fatty acids and so on. Therefore, the food composition of the present invention is effective for nutritional supplementation and nutrition control in patients with hyperlipidemia or obesity. Furthermore, when it is used for improving the nutritional state of healthy persons or as a dietetic food for persons with a tendency of obesity, the desired object can be accomplished without untoward effects on their nutritional homeostasis. Thus, the composition can be used as a convenient and useful food or drink. Moreover, the food of the invention has the advantage that the risk of side effects such as diarrhea, vomiting, nausea, abdominal discomfort, etc. is minimal.

## EXAMPLES

The following preparation examples of the nutritive food composition are further illustrative of the present invention. It should be understood that all % in the examples are by weight.

### Examples 1-13

Sodium caseinate, calcium caseinate, gelatin and sucrose are dissolved in water with stirring. Then, NaCl and other minerals are added and dissolved with stirring to prepare a solution A.

On the other hand, casein is dissolved in water and neutralized and dissolved by addition of NaOH. Then, MgSO<sub>4</sub> and other minerals as well as vitamins and oils are added and dissolved with stirring to prepare a solution B.

The two solutions, A and B, are blended and after stirring and volume adjustment, vitamins, flavors, etc. are added and emulsified to provide a food composition of the invention.

This liquid is filled, in 80 ml portions, into tubes and sterilized to provide a batch of products.

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The ingredients, as well as their amounts, viscosity (30 °C, Type B viscosimeter) and amino acid score (on a 2-5-year-old infant basis) of the above composition of the invention are presented below in Table 1.

The vitamins and minerals used and their amounts are as follows.

Vitamins	
Vitamin A	1155 IU
Vitamin B <sub>1</sub>	0.92 mg
Vitamin B <sub>2</sub>	0.92 mg
Vitamin B <sub>6</sub>	0.92 mg
Vitamin B <sub>12</sub>	2.77 µg
Vitamin C	34.64 mg
Vitamin D	92.36 IU
Vitamin E	6.93 IU
Pantothenic acid	4.62 mg
Niacin	9.24 mg
Folic acid	184.72 µg
Biotin	138.54 µg
Vitamin K	69.27 µg
Choline	115.45 mg

Minerals	
Ca	230.90 mg
PO <sub>4</sub>	230.90 mg
Mg	92.36 mg
Na	323.26 mg
K	600.34 mg
Cl	461.80 mg
Fe	7.39 mg
Zn	3.69 mg
Cu	0.46 mg
Mn	9.24 mg
I	34.64 µg

Table 1

5	Example No.	Example 1	Example 2	Example 3
10	Protein (g/80 ml) (w/w%)	9.5 41.3	10.2 48.1	13.0 65.0
15	Carbohydrate (g/80 ml) (w/w%)	9.2 40.0	7.5 35.4	5.2 26.0
20	Fat (g/80 ml) (w/w%)	4.3 18.7	3.5 16.5	1.8 9.0
25	Energy (Kcal)	114	103	89
30	Protein materials			
35	Casein	5.0	4.9	6.9
40	Sodium caseinate	2.1	-	-
45	Calcium caseinate	2.2	3.7	3.3
50	Whole milk	-	4.7	3.9
55	Skim milk	-	3.0	1.5
60	Gelatin	0.8	-	-
65	Enzymatically degraded gelatin	-	-	2.2
70	Wheat flour	3.0	-	-
75	Cheese	-	2.7	2.0
80	Carbohydrate material			
85	Refined sucrose	7.0	2.4	2.7
90	Fat materials			
95	Rice oil	4.2	0.1	-
100	Chocolate	-	3.0	-
105	Other ingredients			
110	Vitamins	q.s.	q.s.	q.s.
115	Minerals	q.s.	q.s.	q.s.
120	Flavors	q.s.	q.s.	q.s.
125	Viscosity, cp (30°C)	1780	840	2220
130	Amino acid score	100	100	100

Table 1 (continued)

5	Example No.	Example 4	Example 5	Example 6
	Protein (g/80 ml) (w/w%)	12.2 61.0	10.8 53.2	9.0 45.0
10	Carbohydrate (g/80 ml) (w/w%)	3.0 15.0	6.9 41.7	8.0 40.0
15	Fat (g/80 ml) (w/w%)	5.0 25.0	2.8 14.1	3.0 15.0
	Energy (Kcal)	105	94	95
20	Protein materials			
	Casein	6.7	5.6	5.6
	Sodium caseinate	2.2	1.1	-
	Calcium caseinate	3.3	1.1	-
25	Whole milk	-	5.6	3.7
	Skim milk	-	2.9	1.5
	Gelatin	1.4	1.2	0.6
	Enzymatically degraded gelatin	-	-	1.1
30	Wheat flour	-	2.0	5.6
	Cheese	-	-	3.2
	Carbohydrate material			
	Refined sucrose	3.0	1.7	1.7
35	Fat materials			
	Rice oil	5.0	1.0	0.8
	Chocolate	-	-	-
40	Other ingredients			
	Vitamins	q.s.	q.s.	q.s.
	Minerals	q.s.	q.s.	q.s.
	Flavors	q.s.	q.s.	q.s.
45	Viscosity, cp (30°C)	1240	2150	1880
	Amino acid score	100	100	92

50

55

Table 1 (continued)

5	Example No.	Example 7	Example 8	Example 9
	Protein (g/80 ml) (w/w%)	12.0 59.7	8.8 44.2	10.0 50.0
10	Carbohydrate (g/80 ml) (w/w%)	7.0 34.8	8.3 41.7	5.2 26.0
15	Fat (g/80 ml) (w/w%)	1.1 5.5	2.8 14.1	4.8 24.0
	Energy (Kcal)	86	94	104
20	Protein materials			
	Casein	6.9	4.9	5.0
	Sodium caseinate	1.1	1.1	3.3
	Calcium caseinate	2.2	1.7	-
	Whole milk	-	1.5	5.6
25	Skim milk	1.5	0.9	1.5
	Gelatin	0.9	0.6	-
	Enzymatically			
	degraded gelatin	1.1	-	-
	Wheat flour	4.0	2.0	-
30	Cheese	-	3.8	3.2
	Carbohydrate material			
	Refined sucrose	3.3	5.7	0.5
35	Fat materials			
	Rice oil	0.9	1.0	1.0
	Chocolate	-	-	3.0
40	Other ingredients			
	Vitamins	q.s.	q.s.	q.s.
	Minerals	q.s.	q.s.	q.s.
	Flavors	q.s.	q.s.	q.s.
45	Viscosity, cp (30°C)	2310	1250	1220
	Amino acid score	100	100	100



Table 1 (continued)

Example No.	Example 10	Example 11	Example 12	Example 13
Protein (g/80 ml) (w/w%)	9.6 48.7	9.8 51.0	11.2 52.1	9.4 49.5
Carbohydrate (g/80 ml) (w/w%)	6.7 34.0	6.3 32.8	7.1 33.0	6.3 33.2
Fat (g/80 ml) (w/w%)	3.4 17.3	3.1 16.1	3.2 14.9	3.3 17.4
Energy (Kcal)	96	92	102	93
Protein materials				
Casein	4.9	5.6	6.3	4.8
Sodium caseinate	3.1	-	-	1.5
Calcium caseinate	-	2.9	3.0	1.8
Whole milk	3.5	4.3	2.5	3.2
Skim milk	1.8	-	3.8	2.5
Gelatin	0.4	0.7	0.2	-
Enzymatically degraded gelatin	-	-	0.4	-
Wheat flour	1.0	1.4	0.8	1.0
Cheese	3.6	2.4	-	1.4
Carbohydrate material				
Refined sucrose	3.5	3.5	1.7	1.5
Fat materials				
Rice oil	1.2	1.1	1.1	0.9
Chocolate	-	-	3.3	2.6
Other ingredients				
Vitamins	q.s.	q.s.	q.s.	q.s.
Minerals	q.s.	q.s.	q.s.	q.s.
Flavors	q.s.	q.s.	q.s.	q.s.
Viscosity, cp (30°C)	760	900	2500	1000
Amino acid score	100	100	100	100

The food compositions thus obtained in the above Examples were not only effective in augmenting body protein but also suited as a tube feeding system for patients with adult disease. Actually the use of the compositions were all effective in preventing exacerbation of adult disease or preventing onset of the disease.

When the foregoing examples were repeated except that erythritol and/or lactosucrose was used as the carbohydrate in lieu of part or the whole of refined sucrose, all the resulting compositions were also able to produce the nutritional supplementation effect of the invention.

Claims

1. A high-protein, high-viscosity nutritive food composition comprising, on a dry weight basis, 40 to 65 weight % of protein, 5 to 25 weight % of fat and 15 to 40 weight % of carbohydrate and having a viscosity of 500 to 3,000 cp (at 30 °C, Type-B viscosimeter) and an amino acid score (on a 2-5-year-old infant basis) of not less than 80.
2. The high-protein, high-viscosity nutritive food composition of claim 1 wherein the protein accounts for 40 to 53 weight %.
3. The high-protein, high-viscosity nutritive food composition of claim 1 wherein the fat accounts for 10 to 18 weight %.
4. The high-protein, high-viscosity nutritive food composition of claim 1 wherein the carbohydrate accounts for 20 to 35 weight %.
5. The high-protein, high-viscosity nutritive food composition of claim 1 wherein the protein accounts for 40-53 weight % and the fat accounts for 10 to 18 weight %.
6. The high-protein, high-viscosity nutritive food composition of claim 1 wherein the fat accounts for 10 to 18 weight % and the carbohydrate accounts for 20 to 35 weight %.
7. The high-protein, high-viscosity nutritive food composition of claim 1 wherein the protein accounts for 40 to 53 weight % and the carbohydrate accounts for 20 to 35 weight %.
8. The high-protein, high-viscosity nutritive food composition of claim 1 wherein the protein accounts for 40 to 53 weight %, the fat accounts for 10 to 18 weight % and the carbohydrate accounts for 20 to 35 weight %.

# INTERNATIONAL SEARCH REPORT

International Application No. PCT/JP91/00442

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) According to International Patent Classification (IPC) or to both National Classification and IPC Int. Cl. <sup>5</sup> A23L1/29, A61K37/02		
<b>II. FIELDS SEARCHED</b> Minimum Documentation Searched: Classification System: Classification Symbols: IPC A23L1/29, 1/305, 1/48, A61K37/02 Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched: Jitsuyo Shinan Koho 1925 - 1990 Kokai Jitsuyo Shinan Koho 1971 - 1990		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>1</sup>		
Category *	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
Y	JP, A, 62-224259 (K.K. Sanwa Kagaku Kenkyusho), October 2, 1987 (02. 10. 87), (Family: none)	
Y	JP, A, 1-240169 (K.K. Sanwa Kagaku Kenkyusho), September 25, 1989 (25. 09. 89), (Family: none)	
Y	JP, A, 62-232361 (The Green Cross Corp.), October 12, 1987 (12. 10. 87), (Family: none)	
Y	JP, A, 61-58560 (Nippon Oil and Fats Co., Ltd.), March 25, 1986 (25. 03. 86), (Family: none)	
<sup>10</sup> Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claimed or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "Z" document member of the same patent family		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search June 20, 1991 (20. 06. 91)		Date of Mailing of this International Search Report July 1, 1991 (01. 07. 91)
International Searching Authority Japanese Patent Office		Signature of Authorized Officer